

Attorney's Docket No. 035576/233803

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 09/842,466 Confirmation No.: 8005
Applicant(s): Kokubo et al.
Filed: 04/26/2001
Art Unit: 1616
Examiner: H. Sheikh
Title: SOLID PREPARATION COATED WITH A FILM COATING
LAYER AND FILM COATING AGENT

Docket No.: 035576/233803
Customer No.: 00826

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR § 41.41

This Reply Brief is filed pursuant to the "Examiner's Answer" mailed November 28,
2008.

Status of Claims.

Claims 6 – 9, 11, 13 – 20, and 31 – 47 are pending and all claims stand finally rejected as unpatentable over a combination of references as set forth in greater detail below. The prior art rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 is appealed herein.

Claims 1 – 5, 10, 12, and 21 – 30 have been cancelled.

Grounds of Rejection to be Reviewed on Appeal.

Claims 6 – 9, 11, 13 – 20, and 31 – 47 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,820,524 to Berta in view of U.S. Patent No. 6,406,738 to Hogan et al.

Argument.

I. Brief summary of the arguments set forth in the Examiner's Answer

The Examiner's arguments can be broken down into three primary arguments that are summarized as follows:

- 1) The multicolored medicament (caplet/tablet) of Berta has a continuous coating;
- 2) The process steps of the instant claims are not given patentable weight;
- 3) Hogan teaches irradiation to form a multicolored continuous coating.

The Appellant submits that the Examiner has mischaracterized the teachings of both Berta and Hogan, and that neither one of these references suggests or discloses medicament having a coating that is both continuous and multicolored.

II. Berta does not disclose or suggest a multicolored medicament having a continuous coating.

The Examiner maintains that the multicolored coating is a single layer and is therefore continuous. This is an incorrect interpretation of Berta. Specifically, Berta teaches a two-portion coating in which each portion is applied and cured in separate and distinct steps. As described in Appellant's Brief, Berta describes that a first exposed end of the medicament is dipped into a coating bath and then dried. After drying, the second uncoated end is dipped into a second bath and then is dried to provide a multicolored caplet. The following excerpt from Berta explains how the multicolored caplet of Berta is obtained.

The novel process of this invention comprises the steps of providing a holding means having a caplet channel defined therein and inserting a first end of a caplet into said caplet channel while leaving the second end of the caplet exposed. The holding means is then manipulated relative to a bath of gelatinous coating to dip the second exposed end of each caplet into that bath. The resulting gelatinous coating on the second exposed end of the caplet is then permitted, and preferably caused, to dry to form a coated end. During the drying process the caplet may be rotated to assist in uniformly distributing gelatin during drying. Once dry, the coated (second) end of the caplet is then displaced through the caplet channel to

expose its uncoated first end. A gelatinous coating is then applied to the uncoated first end of said caplet. The coating applied to the first end of the caplet is then permitted (or preferably caused) to dry, again with rotation if desired for the purpose of spreading the coating evenly. In accordance with the preferred embodiment method, the baths of gelatinous coating into which the caplet ends are dipped may be of different colors, to thereby create a simulated 2-piece capsule look to the finished caplets with seams about their transverse axes.

See column 5, line 48 – column 6, line 2 (emphasis added). From this excerpt, it can be seen that the coatings described in Berta are applied separately to the two ends of the caplet as two distinct coatings. Invariably a seam or demarcation would be present where the two coatings contact each other. See for example FIG. 8a, which clearly shows a seam or demarcation between the two coated halves of the caplet. As further noted in Berta, “[t]he first and second gelatinous coatings substantially cover the caplet to form a simulated capsule-like medicament with a seam...” See column 10, lines 37-40 (emphasis added). As such, these two distinct coatings cannot be considered continuous. Rather, the caplet of Berta comprises two separate coatings that are separately applied and dried on each half of the caplet. In fact, Berta teaches that to obtain the two different colors, two separate coating baths are used. Thus, Berta does not disclose or suggest a solid preparation having a multicolored continuous film coating layer as recited in independent Claims 31 and 33.

In sharp contrast to Berta, the claimed invention recites a continuous coating. The continuous coating is applied as a single continuous layer that covers the entire medicament. As a result, the multicolored caplet/tablet of the claimed invention does not include two separate coatings or a seam that would be disposed between the two coatings. As noted above, the outer coatings of Berta are applied as two separate coatings that are applied in separate steps. These separate coatings are not continuous.

The Examiner appears to believe that Berta teaches a continuous coating by stating “[i]t is still another object of this invention to provide a heavy layer of gelatin as a single coating to cover imperfections inherent on the caplet core.” See column 4, lines 54-56. In particular, the Examiner’s reliance appears to be based on the use of the term “single.” However, the term

“single” cannot be construed as being continuous. This is particularly true, when the teachings of Berta are considered as a whole. In the context of Berta, the two halves of the caplet are each separately coated with a single layer of gelatin to provide the multicolored caplet. This excerpt does not suggest that the two coatings of Berta that are each applied as a single layer form a continuous coating that covers the entire caplet.

Thus, it can be clearly seen that Berta fails to disclose or suggest a medicament having a multicolored continuous coating.

III. It is improper for the Examiner to ignore the recited process steps

While it is generally true that the patentability of a product-by-process claims is based on the patentability of the product, it is improper to simply ignore such process steps when they arrive at an article that is different than that of the prior art. In the present case, the claimed preparation having a multicolored continuous coating is provided by the recited steps. Specifically, the claimed invention provides a multicolored continuous coating by selectively irradiating portions of the continuous coating to produce a coating having two distinct colors. This step is neither suggested nor disclosed by the cited references, and it is this step that allows for the claimed coating that is both continuous and multi-colored. In contrast, it is not possible to provide a caplet having a coating layer that is both continuous and multicolored using the methods of either Berta or Hogan. As noted above and in Appellant’s Brief, both Berta and Hogan teach forming two separate coatings on separate halves of the caplet to produce their multicolored caplets. Accordingly, the recited process steps provide a coated caplet that is structurally different than the caplets provided by either Berta or Hogan.

IV. Hogan does not teach irradiation to form a multicolored continuous coating

The Examiner asserts that Hogan teaches the step of irradiation to provide a caplet having a multicolored continuous coating. The Examiner is mistaken in this characterization of Hogan. As noted in Appellant’s Brief, Hogan describes a process for preparing a multicolored tablet in which a first coating powder is electrostatically applied to one portion of the tablet followed by exposing the coating to electromagnetic radiation, such as infrared radiation, to cause the powder

to melt and form a liquid. See column 4, lines 32 – 44. Upon cooling, the liquid forms a coating on the surface of the tablet to which it has been applied. In a subsequent step, a second coating powder of a different colorant is electrostatically applied to the uncoated portions of the tablet, followed by exposure to electromagnetic radiation and cooling as described previously to form a multicolored tablet. As in Berta, there would be a demarcation or seam between these two separately applied coating layers. From this discussion, it can be seen that the multicolored coating of Hogan also comprises two distinct coatings that are separately applied to the tablet. As such, Hogan teaches a tablet having two separate coatings covering distinct halves of the tablet and does not have the presently claimed multicolored continuous coating layer.

Further, Hogan teaches irradiation to melt the electrostatically charged powder. There is absolutely no teaching or suggestion in Hogan that the irradiation step in Hogan could effect any color change in the coating material. In fact and as discussed in greater detail below, there is no teaching in either of the references that irradiating the coating would produce any sort of color change in the coatings. As such, the combination of the references fails to disclose or suggest the steps that are necessary to arrive at the claimed invention and therefore fail to disclose or suggest the claimed structure that is arrived at with the claimed method steps. That is, the cited references fail to disclose or suggest a process that can be used to prepare a solid composition having a multicolored continuous film coating layer.

From the foregoing discussion, it is clear that the combination of Berta and Hogan fails to disclose each and every element recited in independent Claims 31 and 33. It is respectfully requested that the rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 be reversed.

V. One of Ordinary Skill in the Art would not be motivated to combine Berta and Hogan.

The Examiner asserts that it would be obvious to one of ordinary skill in the art to incorporate the powder coating material methods of Hogan, which comprise the step of applying radiation, within the multicolored tablets of Berta. The Appellant disagrees with this assertion for several reasons.

1. One of ordinary skill in the art would not be motivated to irradiate the caplet of Berta because to do so would serve absolutely no purpose. Berta already describes a process of preparing a multicolored tablet. The irradiation step of Hogan would serve no purpose. In Hogan the irradiation step is necessary in order to melt and fuse the particles together in order to form a coating. Such a step is unnecessary in the process of Berta and would in fact serve no purpose because the coating of Berta is provided as a liquid that is subsequently dried to form a coating, and as such, there is no reason to apply irradiation to fuse the coating together as in Hogan.

2. Berta and Hogan do not include any teachings that their respective coatings would change color upon irradiation. There is absolutely no basis for suggesting that the irradiation step of Hogan would result in changing the color of the coatings of either Berta or Hogan.

3. The combination fails to provide a predictable result. One cannot predict how irradiation would affect the structure of the coatings of Berta. As discussed in Appellant's Brief, the irradiation step of Hogan is provided to melt the individual particles of Hogan so that upon cooling they are able to fuse together to form a coating. Applying the irradiation step to the coatings of Berta would likely result in melting of the individual coatings on each half of the caplet/tablet. This would result in the caplet losing uniformity in the coating, which in turn, would result in the tablet having an unsightly appearance. As such, using the irradiating step of Hogan in the process of Berta would result in the caplet/tablet being unsatisfactory for its intended purpose. This is a clear indication that a lack of predictability exists in arriving at the claimed invention based on the combination of Berta and Hogan.

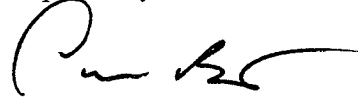
4. Lack of an expectation of success. One of ordinary skill would not have an expectation of success in irradiating the caplets of Berta as taught by Hogan. Irradiating a material to its melting point, as taught in Hogan, would result in the coatings of Berta becoming fluid and flowing on the surface of the tablet. This would be particularly true if heat from irradiation is being introduced into the fluid coating. Portions of the now fluid coating would run together or flow to one side of the caplet making the caplet have an unsightly and aesthetically unappealing appearance. Accordingly, one of ordinary skill would not have an expectation of success in irradiating the caplets of Berta as taught by Hogan.

For these additional reason, Appellant respectfully submits that one of ordinary skill in the art would not be motivated to combine the references as contemplated by the Examiner, and that the rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 should be reversed.

CONCLUSION

In view of the foregoing remarks, it can be seen that the claimed invention is patentable over the cited references because Berta and Hogan, whether considered individually or in combination, fail to disclose or suggest a solid composition having a multicolored continuous film coating layer. Further, one of ordinary skill in the art would not be motivated to modify Berta to include the irradiation step of Hogan as contemplated by the Office. Appellant respectfully requests that the rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 be reversed. A decision from the Board of Patent Appeals and Interferences reversing the final rejection of the pending claims is therefore earnestly solicited.

Respectfully submitted,



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